



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of) Examiner: W. JUNG
R. ABOVITZ, et al.)
Serial No.: 09/978,599) Art Unit: 3737
Filed: October 16, 2001) Confirmation: 5128
For: **DIGITAL MINIMALLY)
INVASIVE SURGERY)
SYSTEM)**
Date of Notice of Appeal:)
March 29, 2006)
Attorney Docket No.:) Cleveland, OH 44114
MAKO 2 00014 US) May 25, 2006

APPEAL BRIEF

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Dear Sir:

A Notice of Appeal was filed March 29, 2006, appealing from the Final Rejection mailed December 30, 2005 rejecting claims 2-15, 17-32, and 34-39.

Payment of the 37 CFR 1.17(c) fee in the amount of \$ 500.00 is authorized to be charged to a Credit Card. The applicants enclose and appropriate form PTO 2038 for this purpose.

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REAL PARTY IN INTEREST

The real parties in interest are the assignee Z-KAT, INC. and its licensee MAKO SURGICAL CORP. both of 2903 Simms Street, Hollywood, FL 33020.

RELATED APPEALS AND INTERFERENCES

None

STATUS OF THE CLAIMS

In the initial Office Action on the merits, numerous claims were either allowed or indicated to contain allowable subject matter. In an effort to obtain a prompt allowance, the applicants placed numerous dependent claims indicated as containing allowable subject matter in independent form and cancelled or added the indicated allowable subject matter to the other independent claims. The application was subsequently transferred to a new Examiner and the status of the claims is now as follows:

Claims 2-15, 17-32, and 34-39 are pending in the application.

Claims 1, 16, and 33 have been cancelled.

Claims 2-15, 17-32, and 34-39 stand rejected.

STATUS OF AMENDMENTS

Amendments A-E have been entered. No amendments have been denied entry.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 2 calls for an image guided surgery system whose computers are programmed with less than all of the software necessary to perform one or more types of image-guided surgery (page 1, line 10-page 3, line 15), the present image-guided surgery includes a computer 10 preprogrammed with a portion of the image-guided surgery software. This portion provides minimal user functionality (page 6, line 33 – page 7, line 10; page 9, line 24 – page 10, line 8). Full user functionality is enabled by adding application-specific software (page 9, line 24 – page 12, line 3).

The system further includes a software-integrated, disposable kit 20 (page 8, line 16 – page 9, line 23). The kit includes an openable, transportable case 22 (page 7, line 26 – 30). The case holds instrumented surgical tools 26, 28, 30 for a preselected surgical procedure (page 7, lines 32-36), and a digital medium 50 with the application-specific software specific to the preselected surgical procedure for upgrading the image-guided surgery software to facilitate performance of the preselected surgical procedure (page 10, line 26 – page 12, line 3).

The case is openable at the surgical site such that the tools are removable at the surgical site for use in the preselected surgical procedure and the digital medium 50 is removable from the case 22 and insertable into the computer 10 to enable full functionality of the image-guided surgery software for the preselected surgical procedure (page 5, lines 15-29; page 7, lines 26-30; page 8, lines 25-29; page 9, lines 14-23; page 10, lines 9-25).

The system further includes a tracking system 16 which locates the surgical tools while in use, the tracking system being disposed at the surgical site (page 7, lines 2-16; page 7, line 16 – page 8, line 15; page 10, lines 30-35). A display 14 is used in conjunction with the computer (page 7, line 6).

This provides hospitals or other surgical sites with a new business model in which they pay to upgrade their computer systems on a per use basis rather than with high initial capital expenditures. This simplifies billing and clarifies insurance reimbursement (page 5, lines 30-37; page 12, lines 6-13).

Claim 5 is directed to an image-guided surgery system which includes software-integrated disposable kits 20 (page 7, line 24 – page 9, line 23). Each kit includes a digital medium 50 with application specific software (page 10, line 26 –

page 12, line 3) and instrumented disposable surgical tools 26, 28, 30 (page 7, lines 32-36).

A computer 10 receives the digital medium 50 and processes the application-specific software (page 10, line 26 – page 12, line 3). A tracking system 16 tracks the surgical tools during a surgical procedure (page 7, line 2 – page 8, line 15). A display 14 is used in conjunction with the computer.

A means 80 deactivates or encrypts the digital medium against reuse at the end of the surgical procedure (page 11, lines 27 – page 12, line 3). Deactivating or encrypting the digital medium ensures that the computer only remains upgraded for the single surgery for which the kit was purchased and helps insure that the single-use tools in the kit are either returned for reprocessing or destroyed.

Claim 7 is again directed to an image-guided surgery system. It includes an integrated computer 10 and a software integrated single use, preselected surgical procedure-specific kit 20 (page 7, line 24 – page 9, line 23). The kit includes a portable, openable housing 22, a label 24 affixed to the housing to identify the preselected surgical procedure to be performed by the kit, sterile packaging (page 8, lines 12-15) in which surgical tools 26, 28, 30 for the preselected surgical procedure are maintained in sterile condition. Other accessories 34, 36, 38, 42, 44, 46, (page 8, line 16 – page 9, line 13), user input devices 40, (page 8, line 30 – page 9, line 1), and a disposable, one-time use digital medium 50 readable by the computer 10 and containing a portion of the image-guided surgery software specific to the preselected surgical procedure (page 10, line 26 – page 12, line 3).

Claim 9 calls for an image-guided surgery system which includes a software-integrated disposable kit 20 (page 7, line 24 – page 9, line 23). The software-integrated disposable kit includes instrumented disposable surgical tools 26, 28, 30 and a digital medium 50 with application-specific software. The digital medium includes programmed one-time-use application-specific software module for use in surgery, and a preprogrammed software module 74 describing surgical tools, implants, and other accessories (page 10, line 26 – page 12, line 3). The instrumented surgical tools 26, 28, 30 and the digital medium 50 are packaged in a common shipping unit 22 from which the tools and digital medium are removable at a surgical site (page 7, line 24 – page 9, line 23).

A tracking system 16 tracks the surgical tools during surgery. A computer 10 receives the software from the digital medium before a surgical procedure and disables it after the procedure (page 11, line 27 – page 12, line 3). A display 14 is used in conjunction with the computer.

Claim 10 is also directed to an image-guided surgery system. It comprises a computer 10, a software-integrated one-time-use kit 20, a tracking system 16, and a display 14. The one-time-use kit 20 (page 7, line 24 – page 9, line 23) includes a shipping case 22, surgical tools 26, 28, 30, and a digital medium 50. The digital medium includes pre-programmed software 74 describing dimensional specification of each of the tools 26, 28, probes 30, guides 34, and any other instrumented accessories 36, 38, 40, 42, 44, 46 which are contained in the kit (page 10, line 26 – page 12, line 3).

Claim 11 is directed to a surgery system including an integrated computer 10 and a display 14 used in conjunction with the computer. Software-integrated kits 22 are each designed for a preselected surgical procedure (page 7, line 24 – page 9, line 23). Each kit includes a common case 22, surgical tools 26, 28 for performing the pre-selected surgical procedure, a digital medium 50 pre-programmed with software 74 of 3D virtual representations, images, or information regarding the surgical tools and any accessories, implants 42, and associated hardware 44, 46 contained in the kit which software is used to create 3D virtual representations of the surgical tools in images on the display 14 (page 10, line 26 – page 11, line 12).

Claim 20 is directed to a method of image-guided surgery using a computer 10, a one-time-use surgical application kit 20 which contains a digital medium 50 with application-specific software, and surgical tools and accessories 36-46, a tracking system 16 which locates the surgical tools while in use, and a display 14. The method includes at the surgical site in preparation for the procedure, removing the digital medium 50 from the kit 20 and inserting the digital medium into the computer 10 (page 5, lines 15-18). The software on the computer 10 is augmented with software from the digital medium 50 to process diagnostic images, register the diagnostic images to the patient's anatomy, register different sets of imaging modalities to each other, and track locations of the surgical tool (page 5, lines 18-27; page 10 line 26 – page 12, line 3). During the surgical procedure, a virtual

representation of the surgical tool 26, 28 is displayed on the image correlating movement of the virtual tool representation on the image with movement of the corresponding surgical tool in physical space (page 10, line 30 – page 11, line 12). The digital medium 50 is deactivated or encrypted against reuse after the surgical procedure (page 5, lines 27-29; page 11, lines 27-35).

Claim 23 is directed to a method of image-guided surgery. A kit 20 is provided which includes (1) instrumented surgical tools and accessories 36-46 and (2) a digital medium 50 which is pre-programmed with (i) at least portions of a graphics processing program 72 and (ii) information 74 concerning the surgical tools and accessories. At the surgical site, the digital medium 50 is removed from the kit and inserted into a processor 10 which, between the software with which the processor is preprogrammed and the software from the digital medium, processes electronic medical diagnostic images, correlates a coordinate system of the patient with a coordinate system of the diagnostic images, tracks a location of the instrumented surgical tool in the coordinate system of the patient, and translates the instrument position into the coordinate system of the diagnostic image (page 10, line 26 – page 12, line 3; page 18, original claim 23). At the surgical site, the surgical tools and accessories are also removed from the kit.

Claim 20 is directed to a surgical kit 20 (page 7, line 24 – page 9, line 23). The kit includes a housing 22, an identification 24 of the surgical procedure to be performed by the kit attached to an exterior of the housing 22, surgical tools 26, 28, in sterile packaging which are used in the identified surgical procedure, medical appliances 42-46 in sterile condition in sterile packaging which are used in the identified surgical procedure, an operator control 40 in sterile condition in sterile packaging for electrical interconnection with a graphics processor which is pre-programmed with image-guided surgical software 60 and provides limited user functionality. The graphics processor 10 is located outside the sterile field. The surgical tools, medical appliances, and the operator control are all removably disposed in the housing 22. The kit 20 further includes a digital media 50 pre-programmed with a portion of an image-guided surgery processing program and descriptive information 72-78 concerning the surgical tools and the appliances in the kit which is removable from the processor to upgrade the preprogrammed image-guided surgery

software 60 to full user functionality for the identified surgical procedure (page 10, line 26 – page 12, line 3).

Claim 31 is directed to an image-guided surgery system. It includes a set of surgical tools 36, 38 which are instrumented to be tracked during image-guided surgery. A processor 10 is preprogrammed 60 with less than all of the software which is used for manipulating diagnostic images during image-guided surgery for tracking the movement of the instrumented surgical tools during the image-guided surgery. A digital medium 50 is preprogrammed 74-78 with a remaining portion of the software for processing the diagnostic image data and tracking movement of the instrumented surgical tools and with descriptive information concerning the instrumented surgical tools (page 8, line 26 – page 12, line 3). A deactivator 80 deactivates the digital medium against reuse at the end of an image-guided surgical procedure (page 11, lines 27-35).

Claim 39 is directed to a method of implementing a computer-implemented procedure. An integrated computer 10 is provided which receives a digital medium 50 and which renders the digital medium inoperative 80 (page 11, lines 27-35). A software disposable kit 22 is opened and the digital medium with application-specific software 72 and any associated elements 74-78 is removed from the kit and inserted into the integrated computer 10 (page 10, line 26 – page 12, line 3). The procedure is performed, after which the digital medium 50 is deactivated or encrypted against reuse in the integrated computer (page 11, lines 27-35). Thereafter, the digital medium 50 is removed from the computer 10.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 2-4 are unpatentable under 35 U.S.C. § 103 over Kienzle (US 6,285,902) in view of Martinez (US 4,577,639) further in view of Lichtenstein (US 4,370,983).

Whether claims 5, 6, 12, 13, 14, and 15 are unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claims 7 and 8 are unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 9 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 10 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 11 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claims 17-22 are unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claims 23-29 are unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 30 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claims 31, 32, and 34-37 are unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 38 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

Whether claim 39 is unpatentable under 35 U.S.C. § 103 over Kienzle in view of Martinez, further in view of Lichtenstein.

ARGUMENTS

Kienzle is illustrative of the acknowledged prior art, which lacks the concept of a kit, the concept of a digital medium for upgrading a minimally programmed computer, deactivation of the digital medium after a surgical procedure, and other features which will be pointed out in greater detail below.

The Examiner cites **Martinez** as disclosing a kit. However, the applicants submit that Martinez is merely illustrative of common surgical practice and does not show a kit in the sense of the present application. As those in the surgical arts know, in standard surgical practice, there is an area of the operating room which is defined as the sterile field. Only sterile tools or items are permitted in the sterile field. It is also commonly known that in this surgical field, that if one were to carry a surgical instrument or tool around the halls or outside of the surgical field in the operating room, it can easily be contaminated. Even if once sterilized at a remote location, (e.g., the hospital's central sterilization center) such exposure to non-sterile areas would cause the tool to be considered not sterile. Rather than have sterilizers in every operating room, surgical tools and other equipment which must be brought into the surgical field is commonly sterilized at a remote site and wrapped in sterile packaging. Martinez refers to the sterile packaging as a sterilized package or kit, although it is not a kit in the sense of the present application. This sterile packaging maintains the instrument in a sterile condition by preventing microbes, germs, and other contaminants from contacting it. In the surgical suite, an assistant typically stands outside of the sterile field and opens the sterile packaging **without touching the contained sterile tool or instrument**. A surgeon or surgeon's assistant within the sterile field removes the tool or instrument from the sterile packaging without touching the exterior of the sterile packaging, only the tool or the sterile interior of the packaging. Thus, it is submitted that Martinez is merely illustrative of the standard surgical practice of delivering tools, instruments, and other objects which will be used in surgery to the operating room in sterile packaging. The sterile packaging of Martinez is analogous to the sterile packaging in which each of the tools and accessories contained in the kit 20 of the present application are packaged (page 8, lines 28-29 of the present application).

Lichtenstein is directed to a computer-control medical care system for use in the treatment and diagnosis of patients. Figure 4 illustrates a microprocessor MC controlled portion of the apparatus that is arranged and constructed for supporting the module and controlling the flow of fluid therethrough. The portion of Figure 4 can be connected with various modules, such as the modules shown in Figure 5 or Figure 6 (column 15, lines 42-53). To be sure that the microcontroller MC/101 appropriates in the appropriate manner to function with the module to which it is actually connected, an interface 62 includes a code detector 105 which reads the code 106 on the replaceable module 83 which identifies the type of module and the nature of the process with which it is designed to operate (column 17, lines 15-33). The computer 101 is preprogrammed with all the necessary elements for operating the interface and controlling the flow of fluid through module 83 (column 17, lines 29-32). The Examiner directs the applicants' attention to column 32, lines 27-52. This paragraph is cumulative with the earlier recitations to the effect that the microcomputer MC merely reads an identification of the interconnected module to determine which of the programs with which it is already programmed should be used with the currently attached module. The referenced paragraph does add the extra concept that if the identification of the replaceable module is stored on a programmable storage means, that programmable storage means might be used to store data as the preprogrammed operation is carried out. It makes no suggestion of upgrading or changing the functionality of the software in the microcomputer MC/101.

Claim 2 is directed to an image-guided surgery system in which a computer is preprogrammed with a portion of the image-guided surgery software that provides minimal user functionality. Full user functionality is enabled by adding application specific software. In Kienzle, the image-guided surgery computer is already preprogrammed with full user functionality. There is no suggestion of placing less than the software necessary for full functionality in the Kienzle computer. Lichtenstein does not cure this shortcoming of Kienzle. Lichtenstein merely suggests that a microprocessor controlled piece of equipment which is interconnectable with any of a plurality of modules read an identification of the module to which it is actually interconnected to be sure that it selects the correct one of the many programs

already in its memory which are appropriate for use with the module to which it is connected. Martinez does not address this issue. Thus, neither Kienzle, nor Lichtenstein, nor the combination thereof teach or fairly suggest preprogramming the computer of an image-guided surgery system with only minimum functionality and providing full user functionality only by adding application specific software.

Further, claim 2 calls for a software-integrated disposable kit which includes a transportable case, surgical tools, and a digital medium. The so-called "kit" of Martinez is merely the sterile packaging in which an individual surgical tool is prepackaged to hold its sterile condition after sterilization. There is no suggestion of including a digital medium in the sterile packaging. Indeed, many sterilization procedures, such as high temperature steam sterilization, would have an adverse affect on a digital medium. Thus, there is no motivation to incorporate a digital medium in the sterile packaging of Martinez. Further, the kit calls for instrumented surgical tools, in the plural. Martinez only suggests the conventional procedure of enclosing a single tool within the sterile packaging. It is further noted that the sterile packaging or "kit" of Martinez is not illustrated in the drawings. It is submitted that Martinez provides no motivation to provide anything more than a conventional gauze wrap or Tyvec envelope, two constructions commonly used as sterile packaging.

Accordingly, it is submitted that claim 2 and claims 3 and 4 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 4 further calls for the computer to provide only minimal user functionality when the digital medium is removed. Because the PROM or RAM of Lichtenstein is not suggested as carrying any programming that alters the functionality of the microcomputer MC/101, it is submitted that there is no suggestion of reducing the functionality of the computer when the medium is removed. Accordingly, it is submitted that claim 4 distinguishes patentably and unobviously over the references of record.

Claim 5 calls for software-integrated disposable kits which include a digital medium with application specific software and instrumented, disposable tools. There is no suggestion in Kienzle, Lichtenstein, or Martinez of a kit which includes both a digital medium with application specific software and instrumented disposable tools. Indeed, none of these references teach or fairly suggest providing a digital

medium with application specific software in a kit along with instrumented surgical tools.

Claim 5 further calls for a means for deactivating or encrypting the digital medium against reuse at the end of the surgical procedure. As indicated above, this enables the kits to be sold on a one-use basis and prevents reuse of the software or the performing of more than one surgery with the purchase of a single kit. The Examiner does not address deactivating or encrypting means. Indeed, neither Kienzle, Martinez, nor Lichtenstein teach or fairly suggest such a means. Accordingly, it is submitted that claim 5 and claims 6, 12, 13, 14, and 15 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 12 further calls for the digital medium to include preprogrammed software for superimposing instrumented tools, accessories, implants, and associated hardware on images in a wire frame or a user-selected custom format. None of the references teach or fairly suggest a digital medium carried by a kit which carries such software. Accordingly, it is submitted that claim 12 distinguishes patentably over the references of record.

Claim 13 calls for the digital medium to have four areas. Such an architecture is not suggested in Lichtenstein or the other references of record. For example, one of the areas stores information relevant to a particular surgical procedure. Neither Lichtenstein nor the other references of record teach or fairly suggest a portable kit carried digital medium which contains information relevant to a surgical procedure. Accordingly, it is submitted that claim 13 distinguishes patentably over the references of record.

Claim 7 calls for a software integrated single-use preselected surgical procedure specific kit. Martinez discloses a surgical instrument which is enclosed in sterile packaging, but provides no illustrations or details of such sterile packaging. Claim 7 calls for the kit to include a housing and a label affixed to the housing to identify a surgical procedure. Martinez makes no suggestion of a housing with an affixed label. Claim 7 further calls for the housing to contain surgical tools contained in sterile packaging. That is, claim 7 calls for both a portable, openable housing and sterile packaging. By contrast, Martinez only alludes to sterile packaging. Claim 7 further calls for other accessories to be disposed in the housing, which other

accessories are also in sterile packaging. By contrast, the sterile packaging of Martinez holds a single surgical tool. There is no suggestion of a housing which contains both surgical tools in sterile packaging and other accessories also in sterile packaging. The kit further includes user input devices disposed in the housing. There is no suggestion in Martinez of including a user input device in the sterile packaging with the surgical tool. Further, claim 7 calls for a one-time usable digital medium which contains a portion of image-guided surgery software specific to the preselected surgical procedure identified by the label. Lichtenstein does not teach or fairly suggest a digital medium which contains a portion of image-guided surgery software specific to a surgical procedure specified by a label on the housing. Lichtenstein and Kienzle do not overcome these shortcomings. Accordingly, it is submitted that claim 7 and claim 8 dependent thereon distinguish patentably and unobviously over the references of record.

Claim 9 calls for a software integrated disposable kit which includes instrumented surgical tools and a digital medium with application specific software. None of the references of record teach or fairly suggest a kit which includes the combination of surgical tools and a digital medium with application specific software. Moreover, claim 9 calls for the digital medium to include a preprogrammed one-time use application specific software module and a preprogrammed module describing the surgical tools, implants, and other accessories. Lichtenstein does not teach or fairly suggest that its PROM or RAM have such an architecture, much less that it be programmed with the specified application specific software module and the module describing surgical tools, implants, and accessories. Accordingly, it is submitted that claim 9 distinguishes patentably over the references of record.

Claim 10 calls for a shipping case in which surgical tools and a digital medium are removably received. None of the references of record teach or fairly suggest a kit which includes a shipping case which receives both tools and digital medium. Kienzle is devoid of any suggestion of such a kit. Martinez merely discloses wrapping a tool in a sterile package. Neither Martinez nor any of the other references teach or fairly suggest the combination of a shipping case containing surgical tools and a digital medium. Accordingly, it is submitted that claim 10 distinguishes patentably and unobviously over the references of record.

Claim 12 calls for a plurality of software integrated kits, each of which is designed for a preselected surgical procedure. None of Kienzle, Lichtenstein, nor Martinez teach or fairly suggest a plurality of kits, each designed for a preselected surgical procedure. Rather, it is submitted that one having read and understood these three references in preparation for performing an image-guided surgery as described by Kienzle would merely collect the appropriate tools from a hospital's surgical tool storage facility individually as requested by the surgeon. There is no suggestion within these references of prepackaging a kit for each of a plurality of preselected surgical procedures. Moreover, claim 11 calls for each kit to include a common case, surgical tools for the preselected procedure, and a digital medium. None of the references teach or suggest a kit which comprises a common case with both surgical tools and a digital medium. Moreover, claim 11 calls for the digital medium to be programmed with software which has 3D virtual representations, images, or other information regarding the surgical tools and any accessories, inputs, and associated hardware contained in the kit for use in creating 3D virtual representations of the surgical tools. None of the references teach or fairly suggest a kit which contains a digital medium that is preprogrammed as specified in claim 11. In Kienzle, the main computer already includes all of this information, hence there is no motivation to provide it on a digital medium from a kit. Martinez does not suggest a kit with a digital medium. There is no suggestion in Lichtenstein of programming the described RAM or PROM with the claimed information, much less including such digital medium with tools in a common case to form a kit designed for a preselected surgical procedure. Accordingly, it is submitted that claim 11 distinguishes patentably and unobviously over the references of record.

Claim 20 is directed to a method of image-guided surgery. At a surgical site in preparation for a surgical procedure, a digital medium is removed from a surgical application specific kit and inserted into a computer. Kienzle makes no suggestion of such a kit-carried digital medium. Martinez makes no suggestions concerning a digital medium. In Lichtenstein, the digital medium of one portion of the system is read by the microcomputer when the two are linked. The tools in Kienzle are not connected to a computer, nor does Lichtenstein make any suggestion of inserting a digital medium into a computer at a surgical site. Claim 20 further calls

for augmenting software already on the computer with software from the digital medium to produce diagnostic images, register the diagnostic images to the patient's anatomy, register different sets of imaging modalities to each other, and track locations of the surgical tool. To the contrary, Kienzle already includes all its software within the computer. There is no suggestion in Kienzle of any advantage to augmenting the computer's software in order to achieve the intended results of Kienzle. Lichtenstein merely identifies the replaceable module and does not suggest augmenting software for performing the claimed method steps. Further, claim 20 calls for deactivating or encrypting the digital medium against reuse after the surgical procedure. There is no suggestion in Kienzle of deactivating any portion of its software after a surgical procedure. Martinez, who does not mention software, does not cure this shortcoming. Similarly, Lichtenstein makes no suggestion of deactivating or encrypting the referenced PROM or RAM against reuse. Indeed, because Lichtenstein proposes to store information on the PROM or RAM, it is submitted that Lichtenstein, who presumably would want access to the stored information at a later date, teaches against such deactivation or encryption. Accordingly, it is submitted that claim 20 and claims 17, 18, 19, 21, and 22 dependent therefrom distinguish patentably over the references of record.

Claim 23 is directed to an image-guided surgery method. A kit is provided which includes (1) instrumented surgical tools and accessories and (2) a digital medium which is preprogrammed with (i) at least a portion of a graphics processing program and (ii) information concerning the surgical tools and accessories. None of the references of record teach or fairly suggest a kit which includes both instrumented surgical tools and a digital medium nor does any reference of record teach or fairly suggest a digital medium from a kit which is preprogrammed with at least a portion of a graphics processing program and information concerning surgical tools and accessories. Kienzle is devoid of any suggestion of a kit and has no need for such a digital medium. Martinez merely wraps individual surgical instruments in sterile packaging, a common procedure in hospitals and clinics. There is no suggestion of a kit with an instrument and correlated software, much less software preprogrammed with the claimed graphics processing program and information concerning the surgical tools and accessories. Lichtenstein merely discloses a PROM

or RAM which identifies a disposable portion of a medical care system to the main portion of the system and which is capable of storing information. There is no suggestion in Lichtenstein, nor any motivation, to provide a kit which groups together instrumented surgical tools and a digital medium preprogrammed to support them. Moreover, Lichtenstein makes no suggestion of a digital medium which includes a graphics or any other active processing program. There is nothing in Lichtenstein which would motivate one to create such kits and alter the computer programming of Kienzle to operate in the manner of claim 23.

Claim 23 further calls for, at the surgical site, removing the digital medium from the kit and inserting it into a processor. Between software with which the processor is preprogrammed and the software from the digital medium, electronic medical diagnostic images are processed, coordinate systems of the patient and diagnostic images of the patient are correlated, instrumented surgical tools are tracked. Kienzle requires no additional software to perform its functions. Neither Martinez nor Lichtenstein provide any motivation to remove some of the software from the Kienzle computer and move it to a digital medium which must be inserted back into the same computer before the computer is restored to function in its intended manner. The computer of Kienzle is already fully programmed. There is nothing in Martinez that would motivate one to remove software and functionality from the computer of Kienzle and place on a portable medium. Similarly, the microcomputer MC/100 of Lichtenstein is fully programmed and functional. There is nothing in Lichtenstein that would motivate Kienzle to remove some of the necessary functionality from its computer and place it on a removable medium. Accordingly, it is submitted that claim 23 and claims 24-29 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 24 further calls for the kit to include medical appliances and a user control. Claim 25 further calls for packaging the surgical tools, the surgical appliances, and the control in sterile packaging in sterile condition prior to placing them in the kit. Thus, claim 25 expressly calls for sterile packaged tools and instruments which are collected together in a kit. Martinez merely shows that packaging a single tool in sterile packaging is known. It makes no suggestion of a kit including tools, appliances, a user control and software with the tools, appliances, and

control in sterile packaging. Claim 28 further calls for deactivating the digital medium against reuse after the surgical procedure. Kienzle makes no suggestion of deactivating or destroying any software. Martinez, who does not mention software, does not cure this defect. Lichtenstein makes no suggestion of deactivating the digital medium against reuse after the surgical procedure.

Claim 30 calls for a surgical kit which includes a housing, an identification of a surgical procedure to be performed using the kit attached to the exterior of the housing, and sterile tools in sterile condition in sterile packaging received in the housing. That is, claim 30 specifically calls for the housing and sterile packaging as two different items. Martinez, which the Examiner asserts shows a kit, merely shows a tool in sterile packaging. There is no suggestion in Martinez of a tool in sterile packaging which, in turn, is received in a housing, much less surgical tools all received in the housing. Claim 30 further calls for medical appliances, also in sterile packaging, and an operator control again in sterile packaging to be received in the housing. Kienzle makes no suggestion of a housing containing tools, appliances, and an operator control, all in sterile packaging. Martinez which merely shows a tool in sterile packaging does not cure this shortcoming. Lichtenstein, which was not cited as addressing the kit combination, does not cure this shortcoming. Moreover, claim 30 calls for the kit to include digital media preprogrammed with a portion of an image-guided surgery processing program which is also disposed in the housing. Again, Kienzle does not disclose such a kit or fairly suggest one. Martinez, which alludes to packaging a single tool in sterile packaging, makes no suggestion of placing software in a housing along with tools in sterile packaging, medical appliances in sterile packaging, and the like. Lichtenstein shows that digital medium are known, but makes no suggestion and provides no motivation to place such digital medium in a housing along with surgical tools, medical appliances, and the like. Accordingly, it is submitted that claim 30 distinguishes patentably and unobviously over the references of record.

Claim 31 is directed to an image guided surgery system which includes a processor that is programmed with less than all of the software which is used for manipulating diagnostic images during the image guided surgery and for tracking movement of the instrumented tools during the image-guided surgery. To the

contrary, the computer of Kienzle is loaded with all of the software necessary to perform these functions. Martinez does not address software and provides no motivation to alter the software programming of Kienzle. In Lichtenstein, the processor MC/101 is fully programmed to perform a plurality of functions. There is no suggestion that it should be preprogrammed with less than all of the software which it needs to perform its intended functions. Moreover, claim 31 calls for a digital medium which is preprogrammed with the remaining portion of the software. Because the computer of Kienzle is fully programmed, there is no need for a digital media to supply the remaining portion. Similarly, in Lichtenstein, with the computer MC/101 fully programmed to perform any of several functions, the PROM or RAM merely identifies the associated module and provides extra data storage capacity. There is no suggestion in Lichtenstein that the PROM or RAM should contain software for upgrading the microprocessor MC/101 to its full functionality.

Moreover, claim 31 calls for a deactivator which deactivates the digital medium against reuse at the end of the surgical procedure. Kienzle describes no deactivation of any of its software after the surgical procedure. Lichtenstein makes no suggestion of deactivating the PROM or RAM against reuse at the end of a surgical procedure or of diminishing the functionality of microprocessor MC/101. Because the deactivation of the digital medium from the kit is not suggested by any reference, it is submitted that it is not suggested by the combination of similarly deficient references. Accordingly, it is submitted that claim 31 and claims 32-37 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 38 calls for an image-guided surgery system which includes a computer with limited user functionality, a digital medium containing software to upgrade the computer temporarily to full functionality, and a means for disabling the software against reuse to upgrade the computer after the preselected surgical procedure. Kienzle makes no suggestion of a temporary, single surgical procedure upgrade of its computer. Martinez which fails to address computers or software medium does not address this shortcoming. Lichtenstein suggests a digital medium with an identification of a system component, but makes no suggestion of incorporating software on such PROM or RAM for upgrading the microcomputer MC/101 which is already fully programmed to perform any of multiple functions, nor

is there any suggestion in Martinez to disable software after a surgical procedure to prevent the software from being reused to upgrade the computer. Indeed, the concept of single-use software programming is missing from Kienzle, Martinez, and Lichtenstein. Accordingly, it is submitted that claim 38 distinguishes patentably and unobviously over the references of record.

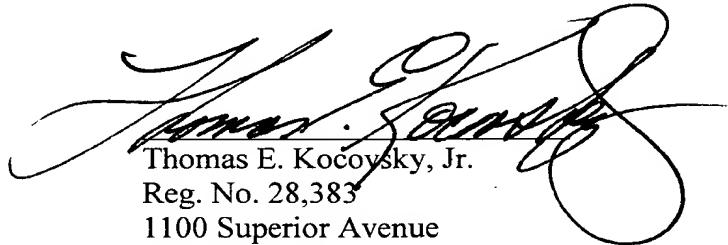
Claim 39 calls for a method of implementing a computer implemented procedure. An integrated computer is provided which (1) receives the digital medium and (2) renders the digital medium inoperative. Kienzle and Lichtenstein both have computers, but neither suggests that their computer has the capability of rendering the received digital medium inoperative. Further, claim 39 calls for inserting the digital medium in to the computer, performing the procedure, and deactivating or encrypting the digital medium against reuse in the integrated computer. Neither Kienzle nor Lichtenstein suggest either the steps of inserting the digital medium into an integrated computer or of deactivating or encrypting it against reuse. Martinez, which does not address software, fails to cure these shortcomings of Kienzle and Lichtenstein. Accordingly, it is submitted that claim 39 distinguishes patentably and unobviously over the references of record.

The applicants again apologize to the Board for the large number of independent claims, each addressing different aspects with different levels of detail. As indicated above, when the Patent Office indicated allowable subject matter in the details of several dependent claims, the applicants attempted to expedite prosecution by placing those claims in independent form. Now that the Patent Office has reversed its position and rejected all these claims over references which, for the reasons set forth above, it is submitted do not address these details, there are now claims with wide variety of scope focusing on a wide variety of details or aspects of the present application, all needing review and consideration.

An early reversal of the Examiner's rejection of all claims is requested.

Respectfully submitted,

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CLAIMS APPENDIX

1. (Cancelled)

2. An image guided surgery system comprising:

a computer pre-programmed with a portion of image guided surgery software that provides minimal user functionality, full user functionality being enabled by adding application specific software, the computer being disposed at a
5 surgical site;

a software-integrated disposable kit including:

an openable, transportable case;

instrumented surgical tools for a preselected surgical procedure, the tools being removably disposed in the case ;

10 a digital medium with the application-specific software specific to the preselected surgical procedure for upgrading the image guided surgery software to facilitate performance of the preselected surgical procedure, the digital medium being removably disposed in the case;

15 the case being openable at the surgical site such that surgical tools are removable from the case at the surgical site for use in the preselected surgical procedure and the digital medium is removable from the case and insertable in the computer to enable full functionality of the image guided surgery software for the preselected surgical procedure;

20 a tracking system which locates the surgical tools while in use, the tracking system being disposed at the surgical site ; and

a display at the surgical site used in conjunction with the computer.

3. The image guided surgery system as set forth in claim 2 further including:

a low cost mobile cart that holds at least the computer, display, and standard peripherals.

4. The image guided surgery system as set forth in claim 2 wherein when the computer receives and reads the digital medium, the image guided surgery software is fully functional for the preselected surgical procedure and when the digital medium is removed, the image guided surgery software provides the minimal user 5 functionality.

5. An image guided surgery system including:
software-integrated disposable kits including:
a digital medium with the application-specific software; and,
instrumented disposable surgical tools;
5 a computer which receives the digital medium and processes the application specific software;
a tracking system which tracks the surgical tools during a surgical procedure;
a display used in conjunction with the computer; and
10 a means for deactivating or encrypting the digital medium against reuse at the end of the surgical procedure.

6. The image guided surgery system as set forth in claim 5 wherein the computer includes:
an input/output interface for capturing still-images and/or live video from an imaging device;
5 a graphic input/output interface for connecting to the display;
an interface for interconnection with at least one of a wired user input device and a wireless user input; and,
an interface for interconnection with tracking sensors for monitoring position and movement of the instrumented surgical tools.

7. An image guided surgery system comprising:
an integrated computer;
a software-integrated, single-use, preselected surgical procedure specific
kit including:

5 a portable, openable housing;
 a label affixed to the housing to identify the preselected
 surgical procedure to be performed using the kit;
 sterile packaging in which surgical tools for the preselected
 surgical procedure are contained in sterile condition, the sterile
10 packaging and tools being removably disposed in the housing;
 other accessories for the preselected surgical procedure in
 sterile condition in sterile packaging, the other accessories and their
 sterile packaging being removably disposed in the housing;
 user input devices removably disposed in the housing; and
15 a disposable, one-time use digital medium readable by the
 computer and containing a portion of image guided surgery software
 specific to the preselected surgical procedure, the digital medium being
 removably disposed in the housing;
 a tracking system which locates the surgical tools while in use; and,
20 a display used in conjunction with the computer.

8. The image guided surgery system as set forth in claim 7 wherein the
user input devices include:

 a disposable, sterilizable, wireless peripheral for use by a surgeon at the
 surgical site for remote communication with the computer.

9. An image guided surgery system comprising:
a software-integrated disposable kit including:
5 instrumented disposable surgical tools;
 a digital medium with application-specific software, the digital
 medium including:

a preprogrammed one-time-use application specific software module to be used in surgery; and

10 a preprogrammed software module describing the surgical tools, implants, and other accessories;

15 the instrumented disposable surgical tools and the digital medium being packaged in a common shipping unit from which the tools and digital medium are removable at a surgical site;

a tracking system which tracks the surgical tools during surgery;

a computer which receives the software from the digital medium before a surgical procedure and disables it after the procedure; and,

a display used in conjunction with the computer.

10. An image guided surgery system comprising:

a computer;

a software-integrated, one-time-use kit including:

5 a shipping case;

surgical tools removably received in the shipping case; and,

a digital medium which includes: preprogrammed software describing dimensional specifications of each of the tools, probes, guides, and any other instrumented accessories contained in the kit, the digital medium being removably received in the shipping case; and

10 a tracking system which tracks the surgical tools while in use; and,

a display connected with the computer.

11. A surgery system comprising:

an integrated computer;

15 a display used in conjunction with the computer;

software-integrated kits, each kit designed for a preselected surgical procedure and including:

a common case;

surgical tools for performing the preselected surgical procedure;

5 a digital medium preprogrammed with software of 3D virtual representations, images, or information regarding the surgical tools, and any accessories, implants, and associated hardware contained in the kit used to create 3D virtual representations of the surgical tools in the images on the display;

the surgical tools and the digital medium both being removably disposed in the common case.

12. The image guided surgery system as set forth in claim 5, the digital medium includes:

5 preprogrammed software for superimposing instrumented tools, accessories, implants, and associated hardware on the images in a wire frame or a user selected custom format.

13. The image guided surgery system as set forth in claim 5 wherein the digital medium includes:

an area which stores the software application which enables full user functionality;

5 an area which stores specifications and characteristics of the instrumented surgical tools;

an area which stores 3D virtual representations, images, or information of the instrumented tools and accessories contained in the kit; and

10 an area which stores additional information relevant to a particular surgical procedure.

14. The image guided surgery system as set forth in claim 5 wherein the tracking system includes:

one of acoustic sensors, infrared sensors, video cameras, that are utilized to determine a location of the instrumented surgical tools.

15. The image guided surgery system as set forth in claim 5 wherein the tracking system includes:

a mobile cart for positioning a tracking camera in a surgical suite.

16. (Cancelled)

17. The method as set forth in claim 20 further including:

using the computer as a planning station before a surgical procedure to define surgical entry points and trajectories.

18. The method as set forth in claim 20 further including:

5 archiving on the digital medium a record or history of the performed surgical procedure, including the downloaded diagnostic images, selected instruments, implants, length of surgical time, notes, or other relevant information obtained during the surgical procedure.

19. The method as set forth in claim 20 further including:

replaying archived data for review and diagnostic follow-up.

20. A method of image guided surgery using a computer, a one-time-use surgical application specific kit that contains a digital medium with application specific software and surgical tools and accessories, a tracking system that locates the surgical tools while in use, and a display, the method comprising:

5 at a surgical site in preparation for a surgical procedure, removing the digital medium from the kit and inserting the digital medium into the computer;

augmenting software on the computer with the software from the digital medium to process diagnostic images, register the diagnostic images to a patient's anatomy, register different sets of imaging modalities to each other, and track 10 locations of the surgical tool;

during the surgical procedure, displaying a virtual representation of the surgical tool on the image, correlating movement of the virtual tool representation on the image with movement of the corresponding surgical tool in physical space;

15 deactivating or encrypting the digital medium against reuse after the surgical procedure.

21. The method as set forth in claim 20 further including:
preventing reuse of the surgical tools.

22. The method as set forth in claim 20 further including:
disposing of the surgical instruments and the digital medium without reuse after the surgical procedure.

23. A method of image guided surgery comprising:
5 providing a kit which includes (1) instrumented surgical tools and accessories and (2) a digital medium which is preprogrammed with (i) at least a portion of a graphics processing program and (ii) information concerning the surgical tools and accessories;

10 at a surgical site, removing the digital medium from the kit and inserting it into a processor which, between software with which the processor is preprogrammed and the software from the digital medium, processes electronic medical diagnostic images, correlates a coordinate system of a patient with a coordinate system of the diagnostic images, tracks a location of the instrumented surgical tools in the coordinate system of the patient, and translates the instrument position into the coordinate system of the diagnostic image;

at the surgical site, removing the surgical tools and accessories from the kit.

24. The method as set forth in claim 23 wherein the surgical kit further includes:

medical appliances, and
5 a user control for interconnection with the processor to control image displays; and the method further includes:

at the surgical site, removing the medical appliances and the user control from the kit.

25. The method as set forth in claim 24 further including:
prior to placing the surgical tools, the surgical appliances, and the user control in the surgical kit, packaging the surgical tools, the surgical appliances, and user control in sterile condition in sterile packaging.

26. The method as set forth in claim 24 further including:
prior to placing the digital medium in the kit, programming the medium, with information about the surgical tools and the medical appliances in the kit.

27. The method as set forth in claim 23 further including:
prior to placing the digital medium in the kit, programming the digital medium with dimensional information about and depictions of the surgical tools.

28. The method as set forth in claim 23 further including:
after the surgical procedure, deactivating the digital media against reuse.

29. The method as set forth in claim 28 further including:
after the surgical procedure, disposing the surgical instruments and the secure digital media without reuse.

30. A surgical kit comprising:

- a housing;
- an identification of a surgical procedure to be performed using the kit, the identification being attached to an exterior of the housing;
- 5 surgical tools in sterile condition in sterile packaging which are used in the identified surgical procedure, the tools being removably received in the housing;
- medical appliances in sterile condition in sterile packaging which are used in the identified surgical procedure, the medical appliances in sterile packaging being removably disposed in the housing;
- 10 an operator control in sterile condition in sterile packaging for electrical interconnection with a graphics processor which is preprogrammed with image guided surgery software that provides limited user functionality outside a sterile field, the operator control in sterile packaging being removably disposed in the housing; and,
- a digital media preprogrammed with a portion of an image guided surgery processing program and descriptive information concerning the surgical tools and the appliances in the kit which is readable by the processor to upgrade the preprogrammed image guided surgery software to full user functionality for the identified surgical procedure, the digital media being removably disposed in the housing.

31. An image guided surgery system comprising:

- a set of surgical tools which are instrumented to be tracked during image guided surgery;
- 5 a processor which is preprogrammed with less than all of the software which is used for manipulating diagnostic images during the image guided surgery and for tracking the movement of the instrumented surgical tools during the image guided surgery;
- a digital media which is preprogrammed with a remaining portion of the software for processing the diagnostic image data and tracking movement of the 10 instrumented surgical tools and with descriptive information concerning the instrumented surgical tools; and

a deactivator which deactivates the digital media against reuse at the end of an image guided surgical procedure.

32. The system as set forth in claim 31 wherein the processor includes:
a reader which receives and reads the digital media.

33. (Cancelled)

34. The system as set forth in claim 31 further including a surgical kit which includes:
an indication of a surgical procedure with which the kit is to be utilized;
the instrumented surgical tools for use in the indicated surgical procedure;
5 and,
the digital media.

35. The system as set forth in claim 34 wherein the kit further includes:
surgical appliances used in the indicated procedure; and
a user input control for controlling the processor, the user input control,
the surgical appliances, and the surgical tools all being in sterile condition in the kit.

36. The system as set forth in claim 31 wherein the processor includes:
an interface for interconnection with a source of three-dimensional
electronic diagnostic images;
an interface for interconnection with a human-readable display for
5 displaying diagnostic images and superimposed representations of the surgical tools;
an interface for interconnection with a user input control; and,
an interface for interconnection with optical sensors for monitoring
position and movement of the instrumented surgical tools.

37. The system as set forth in claim 31 wherein the digital media includes:
a first memory portion which stores the remaining software portion;

5 a second memory portion which stores descriptive characteristics of the
instrumented surgical tools;

a third memory section which stores shape displays corresponding to the
surgical tools for display superimposed on a display of the diagnostic image; and,

a fourth memory portion which carries additional information.

38. An image guided surgery system having a tracking system for
tracking movement of surgical tools, a human-viewable display, and a computer with
limited user functionality for retrieving surgical information, displaying and
manipulating diagnostic images on the display, surgical planning, and superimposing
5 representations of the surgical tools on the images on the display, further including:

a single use digital medium containing software to upgrade the computer
temporarily to full user functionality for a preselected surgical procedure; and,

a means for disabling the software from being reused to upgrade the
computer after the preselected surgical procedure.

39. A method of implementing a computer-implemented procedure, the
method comprising:

providing an integrated computer which receives a digital medium and
which renders the digital medium inoperative;

5 opening a software-integrated disposable kit and removing a digital
medium with application specific software and any associated elements;

inserting the digital medium into the integrated computer;

performing the procedure;

deactivating or encrypting the digital medium against reuse in the
10 integrated computer;

removing the digital medium from the integrated computer.